U.S. Department of Justice

Carmen M. Ortiz
United States Attorney
District of Massachusetts

Main Reception: (617) 748-3100

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Suite 9200
Boston, Massachusetts 02210

October 21, 2010

Geoffrey E. Hobart
Matthew J. O'Connor
Covington & Burling LLP
1201 Pennsylvania Avenue, NW
Washington, DC 20004-2401

Re: United States v. SB Pharmco Puerto Rico, Inc.

Dear Counsel:

This letter sets forth the Agreement between the United States Attorney for the District of Massachusetts ("the U.S. Attorney") and the United States Department of Justice (collectively, the "United States") and your client, SB Pharmco Puerto Rico, Inc. (hereinafter "SB Pharmco"), in the above-referenced case. The Agreement is as follows:

1. Change of Plea

At the earliest practicable date SB Pharmco shall waive indictment and plead guilty to the one-count Information attached hereto as Exhibit A. Count One of the Information charges that from in or about March 2003 to October 2004, SB Pharmco introduced for delivery into interstate commerce various quantities of adulterated drugs Paxil CR, Avandamet, Kytril, and Bactroban in violation of 21 U.S.C. §§ 331(a), 333(a)(2) and 351(a)(2)(B). SB Pharmco expressly and unequivocally admits that it committed these offenses and further admits that it acted with the intent to defraud or mislead. Defendant expressly and unequivocally further admits that it is in fact guilty of this offense, and agrees that it will not make any statements inconsistent with this explicit admission. SB Pharmco agrees to waive venue, to waive any applicable statutes of limitations, and to waive any legal or procedural defects in the Information.

2. Penalties

SB Pharmco faces the following maximum penalties on Count One of the Information:

a. A fine of $500,000, or twice the gross gain derived from the offense or twice the gross loss to a person other than the defendant, whichever is greatest. *See* 18 U.S.C. §§ 3571(c)(5) and (d). Given SB Pharmco's gross gain from its sales of Paxil CR, Avandamet, Kytril and Bactroban that were deemed adulterated between March 2003 and October 2004 totaled $98,834,224, the maximum possible fine in connection with this count is $197,668,448.

b. A term of probation of not more than five (5) years. *See* 18 U.S.C. § 3561(c)(2);

c. Restitution to any victims of the offense. *See* 18 U.S.C. §§ 3556 and 3663; and

d. A mandatory special assessment of $400. *See* 18 U.S.C. § 3013..

3. Sentencing Guidelines

The parties agree that the fine provisions of the United States Sentencing Guidelines ("U.S.S.G.") applicable to organizational defendants for felony violations of the Food, Drug, and Cosmetic Act, see U.S.S.G. § 8C2.1, are calculated as follows, and that this calculation takes into account SB Pharmco's conduct under 18 U.S.C. §§ 3553 and 3572:

a. The parties agree that the base fine is $98,834,224, which is the pecuniary gain to the organization from the offense. *See* U.S.S.G. §§ 8C2.4(a), 8C2.3.

b. Pursuant to U.S.S.G. § 8C2.5, the culpability score is six (6), which is determined as follows:

i. Base culpability score is five (5) pursuant to U.S.S.G. § 8C2.5(a);

ii. Add three (3) points pursuant to U.S.S.G. § 8C2.5(b)(2) in that the organization had 200 or more employees and an individual within high-level personnel of organization participated in, condoned, or was willfully ignorant of the offense; and

iii. Deduct two (2) points pursuant to U.S.S.G. § 8C2.5(g)(2) in recognition of SB Pharmco's full cooperation and clearly

demonstrated recognition and affirmative acceptance of responsibility for its criminal conduct.

iv. Pursuant to U.S.S.G. § 8C2.6, the appropriate multiplier range associated with a culpability score of six (6) is 1.20 to 2.40.

v. Thus, the advisory Guideline Fine Range is $118,601,069 to $197,668,448. *See* U.S.S.G. §§ 8C2.7(a), (b); 18 U.S.C. §§ 3571(c), (d).

4. Agreed Disposition

The United States and SB Pharmco agree pursuant to Fed. R. Crim. P. 11(c)(1)(C) that the appropriate disposition of this case is as follows, and will result in imposition of a reasonable sentence that is sufficient, but not greater than necessary, taking into consideration of all of the factors set forth in 18 U.S.C. §§ 3553(a) and 3572:

a. A criminal fine of $140,000,000 - to be paid within one week of the date of sentencing.

b. Mandatory special assessments totaling $400 pursuant to 18 U.S.C. § 3013, to be imposed as follows:

c. Criminal Forfeiture in the amount of $10,000,000.

d. In light of the pending civil action, United States of America ex rel. Cheryl Eckard v. GlaxoSmithKline, et al., Civil Action No. 04-10375 (D. Mass.), and the Civil Settlement Agreement between SmithKline Beecham Corporation d/b/a/ GlaxoSmithKline and the United States (which is being signed contemporaneously with this Plea Agreement, and is attached hereto as Exhibit B) which requires the payment of $600,000,000, plus interest, the parties agree that the complication and prolongation of the sentencing process that would result from an attempt to fashion a proper restitution order outweighs the need to provide restitution to any non-federal victims in this case given that numerous unknown individuals and insurance companies purchased or reimbursed for the drug products in question, and that tracing reimbursements to the various unknown insurance companies and patients and determining the apportionment of payment pertaining to the products at issue would be extraordinarily difficult, if not impossible. *See* 18 U.S.C. § 3663(a)(1)(B)(ii). Accordingly, the United States agrees that it will not seek a separate restitution order as to SB Pharmco as part of the resolution of the Information and the Parties agree that the appropriate disposition of this case does not include a restitution order.

The United States may, at its sole option, be released from its commitments under this Agreement, including, but not limited to, its agreement that this paragraph constitutes the appropriate disposition of this case, if at any time between Defendant's execution of this Agreement and sentencing, SB Pharmco:

a. Fails to admit a complete factual basis for the plea;

b. Fails to truthfully admit its conduct in the offenses of conviction;

c. Falsely denies, or frivolously contests, relevant conduct for which SB Pharmco is accountable under U.S.S.G. § 1B1.3;

d. Gives false or misleading testimony in any proceeding relating to the criminal conduct charged in this case and any relevant conduct for which SB Pharmco is accountable under U.S.S.G. § 1B1.3;

e. Engages in acts which form a basis for finding that SB Pharmco has obstructed or impeded the administration of justice under U.S.S.G. § 3C1.1;

f. Commits a crime; or

g. Attempts to withdraw its guilty plea.

SB Pharmco expressly understands that it may not withdraw its plea of guilty unless the Court rejects this Agreement under Fed. R. Crim. P. 11(c)(5).

5. No Further Prosecution of SB Pharmco

Pursuant to Fed. R. Crim. P. 11(c)(1)(A), the United States agrees that, other than the charges in the attached Information, it shall not further prosecute SB Pharmco for any additional federal criminal charges or charges under the Food Drug and Cosmetic Act against Defendant with respect to the conduct that:

(a) falls within the scope of the Information to which SB Pharmco is pleading guilty, or

(b) was either the subject of the grand jury investigation in the District of Massachusetts or was known to the United States Attorney's Office for the District of Massachusetts or the Office of Consumer Litigation of the Department of Justice prior to the date of this Agreement relating to:

(i) the production, manufacturing, processing, packing and/or holding of drugs at SB Pharmco's Cidra, Puerto Rico manufacturing facility between the years 2001 and 2005; or

(ii) conduct, communications and reporting regarding the Food and Drug Administration's oversight, regulatory inspections and actions regarding the Cidra, Puerto Rico manufacturing facility between the years 2001 and 2005.

The United States does not decline criminal prosecution of SB Pharmco for any other conduct beyond that set forth above. Without limitation, for the drugs manufactured at Cidra, this release expressly does not extend to any conduct relating to post-marketing studies or analyses; marketing or promotion; or conduct, communications and/or reporting to the FDA or physicians or customers regarding the safety, efficacy, and/or recommended uses of the drugs concerning issues other than manufacturing, processing, packing and/or holding of the drugs at Cidra.

This declination is expressly contingent upon:

a. the guilty plea of SB Pharmco to the Information attached hereto as Exhibit A being accepted by the Court and not withdrawn or otherwise challenged; and

b. SB Pharmco's performance of all of its obligations as set forth in this Agreement and the attached Civil Settlement Agreement.

If SB Pharmco's guilty plea is not accepted by the Court or is withdrawn for any reason, or if SB Pharmco should fail to perform any obligation under this Agreement or the Civil Settlement Agreement, this declination of prosecution shall be null and void.

The United States expressly reserves the right to prosecute any individual, including but not limited to present and former officers, directors, employees, and agents of SB Pharmco, in connection with the conduct encompassed by this plea agreement, within the scope of the grand jury investigation, or known to the United States.

6. Payment of Mandatory Special Assessment

SB Pharmco shall pay the mandatory special assessment to the Clerk of the Court on or before the date of sentencing.

7. Waiver of Right to Appeal and to Bring Other Challenge

a. SB Pharmco has conferred with its attorney and understands that it has the right to challenge its convictions in the United States Court of Appeals for the First Circuit ("direct appeal"). SB Pharmco also understands that it

may, in some circumstances, be able to challenge its convictions in a future proceeding (such as, for example, in a collateral challenge pursuant to 28 U.S.C. § 2255 or 28 U.S.C. § 2241). SB Pharmco waives any right it has to challenge its conviction on direct appeal or in any future proceeding.

b. SB Pharmco has conferred with its attorney and understands that defendants ordinarily have a right to appeal their sentences and may sometimes challenge their sentences in future proceedings. SB Pharmco understands, however, that once the Court accepts this Rule 11(c)(1)(C) plea agreement, the Court is bound by the parties' agreed-upon sentence. SB Pharmco may not contest the agreed-upon sentence in an appeal or challenge the sentence in a future proceeding in federal court. Similarly, the Court has no authority to modify an agreed-upon sentence under 18 U.S.C. § 3582(c), even if the Sentencing Guidelines are later modified in a way that appears favorable to Defendant. Given that a defendant who agrees to a specific sentence cannot later challenge it, and also because SB Pharmco desires to obtain the benefits of this Agreement, SB Pharmco agrees that it will not challenge the sentence imposed in an appeal or other future proceeding. SB Pharmco also agrees that it will not seek to challenge the sentence in an appeal or future proceeding even if the Court rejects one or more positions advocated by any party at sentencing.

c. The United States agrees that it will not appeal the imposition by the Court of the sentence agreed to by the parties as set out in Paragraph 4, even if the Court rejects one or more positions advocated by a party at sentencing.

8. Cooperation

SB Pharmco shall cooperate completely and truthfully in any trial or other proceeding arising out of any ongoing civil, criminal or administrative investigation of its current and former officers, agents, employees, and customers in connection with the matters described in the Information. SB Pharmco shall make reasonable efforts to facilitate access to, and to encourage the cooperation of, its current and former officers, agents, and employees for interviews sought by law enforcement agents, upon request and reasonable notice in connection with matters described in the Information. SB Pharmco shall also take reasonable measures to encourage its current and former officers, agents, and employees to testify truthfully and completely before any grand jury, and at any trial or other hearing, at which they are requested to do so by any government entity in connection with matters described in the Information.

In addition, SB Pharmco shall furnish to law enforcement agents, upon request, all documents and records in its possession, custody or control relating to the conduct that is within the scope of any ongoing federal investigation, trial or other criminal proceeding in connection with matters described in the Information, and that are not covered by the attorney-client

privilege or work product doctrine.

Provided, however, notwithstanding any provision of this Agreement, that: (1) SB Pharmco is not required to request of its current or former officers, agents, or employees that they forego seeking the advice of an attorney nor that they act contrary to that advice; (2) SB Pharmco is not required to take any action against its officers, agents, or employees for following their attorney's advice; and (3) SB Pharmco is not required to waive any privilege or claim of work product protection.

9. Probation Department Not Bound By Agreement

The sentencing disposition agreed upon by the parties and their respective calculations under the Sentencing Guidelines are not binding upon the United States Probation Office.

10. Forfeiture

SB Pharmco will forfeit to the United States assets subject to forfeiture pursuant to 21 U.S.C. § 334 and 28 U.S.C. § 2461(c) as a result of its guilty plea.

SB Pharmco admits that the value of the quantities of Paxil CR and Avandamet that were adulterated and distributed in violation of 21 U.S.C. § 331, totaled at least $10,000,000 in United States currency. SB Pharmco acknowledges and agrees that the quantities of Paxil CR and Avandamet which were adulterated and distributed in violation of 21 U.S.C. § 331 cannot be located upon exercise of due diligence, or have been transferred or sold to, or deposited with, a third party, placed beyond the jurisdiction of the Court, substantially diminished in value, or commingled with other property which cannot be divided without difficulty. Accordingly, SB Pharmco agrees that the United States is entitled to forfeit as "substitute assets" any other assets of SB Pharmco up to the value of the now missing directly forfeitable assets.

SB Pharmco agrees that, no later than one week after sentencing, it shall remit the amount of $10,000,000 in United States currency to the United States Marshals Service pursuant to wire instructions provided by the United States Attorney's Office. SB Pharmco and the United States agree that this payment shall satisfy any and all forfeiture obligations that SB Pharmco may have as a result of its guilty plea.

Forfeiture of substitute assets shall not be deemed an alteration of SB Pharmco's sentence. The forfeitures set forth herein shall not satisfy or offset any fine, restitution, cost of imprisonment, or other penalty imposed upon SB Pharmco, nor shall the forfeiture be used to offset SB Pharmco's tax liability or any other debt owed to the United States.

SB Pharmco agrees to consent to the entry of orders of forfeiture for the $10,000,000 in United States currency, and waives the requirements of Federal Rules of Criminal Procedure 32.2 and 43(a) regarding the notice of the forfeiture in the charging instrument, entry of a preliminary order of forfeiture, announcement of the forfeiture at sentencing, and incorporation of the

forfeiture in the judgment. SB Pharmco acknowledges that it understands that the forfeiture of assets is part of the sentence that may be imposed in this case and waives any failure by the court to advise it of this, pursuant to Rule 11(b)(1)(J), at the time the guilty plea is accepted.

In addition to all other waivers or releases set forth in this Agreement, SB Pharmco hereby waives any and all claims arising from or relating to the forfeitures set forth in this section, including, without limitation, any claims arising under the Double Jeopardy Clause of the Fifth Amendment, or the Excessive Fines Clause of the Eighth Amendment, to the United States Constitution, or any other provision of state or federal law.

The United States District Court for the District of Massachusetts shall retain jurisdiction to enforce the provisions of this section.

11. Fed. R. Crim. P. 11(c)(1)(C) Agreement

SB Pharmco's plea will be tendered pursuant to Fed. R. Crim. P. 11(c)(1)(C). SB Pharmco cannot withdraw its plea of guilty unless the sentencing judge rejects this Agreement or fails to impose a sentence consistent herewith. If the sentencing judge rejects this Agreement or fails to impose a sentence consistent herewith, this Agreement shall be null and void at the option of either the United States or SB Pharmco, with the exception of paragraph 13 (Waiver of Defenses) which shall remain in full effect.

SB Pharmco may seek sentencing by the District Court immediately following the Rule 11 plea hearing. The United States does not object to the Court proceeding to sentence SB Pharmco immediately following the Rule 11 plea hearing or in the absence of a Presentence Report in this case. SB Pharmco understands that the decision whether to proceed immediately following the plea hearing with the sentencing proceeding, and to do so without a Presentence Report, is exclusively that of the United States District Court.

12. Civil and Administrative Liability

By entering into this Agreement, the Government does not compromise any civil or administrative liability, including but not limited to any False Claims Act or tax liability, which SB Pharmco may have incurred or may incur as a result of its conduct and its plea of guilty to the attached Information.

SB Pharmco's civil liability to the United States in connection with certain of the matters under investigation by the Government is resolved in the Civil Settlement Agreement with GlaxoSmithKline LLC, attached as Exhibit B, according to the terms set forth in that Agreement.

13. Waiver of Defenses

If SB Pharmco's guilty plea is not accepted by the Court for whatever reason, if SB Pharmco's guilty plea is later withdrawn or otherwise successfully challenged by SB Pharmco for whatever reason, or if SB Pharmco breaches this Agreement, SB Pharmco hereby waives, and agrees it will not interpose, any defense to any charges brought against it which it might otherwise have under the Constitution for pre-indictment delay, any statute of limitations, or the Speedy Trial Act, except any such defense that SB Pharmco may already have for conduct occurring before August 27, 2002, as further described in the parties' tolling agreement dated May 3, 2010, attached hereto as Exhibit C. This waiver is effective provided that charges are filed within six months of the date on which such guilty plea is rejected, withdrawn, or successfully challenged, or a breach is declared by the United States.

14. Breach of Agreement

If the United States determines that SB Pharmco has failed to comply with any provision of this Agreement, or has committed any crime following its execution of this Agreement, the United States may, at its sole option, be released from its commitments under this Agreement in its entirety by notifying SB Pharmco, through counsel or otherwise, in writing. The United States may also pursue all remedies available under the law, even if it elects not to be released from its commitments under this Agreement. SB Pharmco recognizes that no such breach by it of an obligation under this Agreement shall give rise to grounds for withdrawal of its guilty plea. SB Pharmco understands that should it breach any provision of this Agreement, the United States will have the right to use against SB Pharmco before any grand jury, at any trial or hearing, or for sentencing purposes, any statements which may be made by SB Pharmco, and any information, materials, documents or objects which may be provided by it to the government subsequent to this Agreement, without any limitation.

SB Pharmco understands and agrees that this Rule 11(c)(1)(C) plea agreement and its agreed-upon criminal disposition:

a. are wholly dependant upon SB Pharmco's timely compliance with the material provisions of the attached Civil Settlement Agreement, and that

b. failure by SB Pharmco to comply fully with the material terms of this Agreement or the attached Civil Settlement Agreement will constitute a breach of this Agreement.

In the event SB Pharmco at any time hereafter breaches any material provision of this Agreement, SB Pharmco understands that (1) the United States will as of the date of that breach be relieved of any obligations it may have in this Agreement and the attached Civil Settlement Agreement, including but not limited to the promise not to further prosecute SB Pharmco as set forth in this Agreement; and (2) SB Pharmco will not be relieved of its obligation to make the payments set forth in this Agreement and the attached Civil Settlement Agreement, nor will it be

entitled to return of any monies already paid. Moreover, in the event of a breach, SB Pharmco understands and agrees that the United States may pursue any and all charges that might otherwise have been brought but for this Agreement, and SB Pharmco hereby waives, and agrees it will not interpose, any defense to any charges brought against it which it might otherwise have under the Constitution for pre-indictment delay, any statute of limitations, or the Speedy Trial Act, except any such defense that SB Pharmco may already have for conduct occurring before April 27, 2002.

15. Who Is Bound By Agreement

With respect to matters set forth in Paragraph 5, this Agreement is binding upon SB Pharmco and the Office of the United States Attorney for the District of Massachusetts, the United States Attorney's Offices for each of the other 93 judicial districts of the United States, and the Office of Consumer Litigation of the Department of Justice. The non-prosecution provisions in Paragraph 5 are also binding on the Criminal Division of the United States Department of Justice, with the exception of any investigations of SB Pharmco that are or may be conducted in the future by the Fraud Section of the Criminal Division regarding possible violations of the Foreign Corrupt Practices Act and related offenses in connection with the sales and marketing of SB Pharmco's products to foreign customers, which investigations are specifically excluded from the release in Paragraph 5. A copy of the letter to United States Attorney Carmen M. Ortiz from the Assistant Attorney General, Criminal Division, Department of Justice, authorizing this Agreement is attached as Exhibit D. SB Pharmco understands that this Agreement does not bind any state or local prosecutive authorities, the Tax Division of the U.S. Department of Justice or the Internal Revenue Service of the U.S. Department of the Treasury.

16. Corporate Authorization

SB Pharmco's acknowledgment of this Agreement and execution of this Agreement on behalf of the corporation is attached as Exhibit E. SB Pharmco shall provide to the U.S. Attorney and the Court a certified copy of a resolution of the governing authority of SB Pharmco affirming that it has authority to enter into the Plea Agreement and has (1) reviewed the Information in this case and the proposed Plea Agreement; (2) consulted with legal counsel in connection with the matter; (3) agreed to enter into the proposed Plea Agreement; (4) agreed to authorize SB Pharmco to plead guilty to the charges specified in the Information; and (5) agreed to authorize the corporate officer identified below to execute the Plea Agreement and all other documents necessary to carry out the provisions of the Plea Agreement. A copy of the resolution is attached as Exhibit F. SB Pharmco agrees that either a duly authorized corporate officer or a duly authorized attorney for SB Pharmco, at the discretion of the Court, shall appear on behalf of SB Pharmco and enter the guilty plea and will also appear for the imposition of sentence.

17. Complete Agreement

This Agreement and the attachments hereto, together with the Civil Settlement Agreement and attachments thereto, and the separate side letter with GlaxoSmithKline LLC and attachments thereto, set forth the complete and only agreement between the parties relating to the disposition of this case. No promises, representations or agreements have been made other than those set forth in this Agreement and its attachments, and the Civil Settlement Agreement and its attachments, and the separate side letter with GlaxoSmithKline LLC and its attachments. This Agreement supersedes prior understandings, if any, of the parties, whether written or oral. This Agreement can be modified or supplemented only in a written memorandum signed by the parties or on the record in court.

If this letter accurately reflects the Agreement between the United States and your client, SB Pharmco, please have the authorized representative of SB Pharmco sign the Acknowledgment of Agreement below. Please also sign below as Witness. Return the original of this letter to Assistant U.S. Attorney Susan G. Winkler.

Very truly yours,

Carmen M. Ortiz

CARMEN M. ORTIZ
UNITED STATES ATTORNEY
DISTRICT OF MASSACHUSETTS

By: Susan G. Winkler
Susan G. Winkler

Shannon T. Kelley
Shannon T. Kelley
Assistant U.S. Attorneys
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TONY WEST
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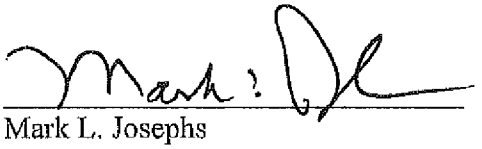
By: 

Mark L. Josephs
Trial Attorney
Office of Consumer Litigation
U.S. Department of Justice

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA	)	Crim. No.
	)	
v.	)	Violation:
	)	
SB PHARMCO PUERTO RICO, INC.	)	21 U.S.C. §§ 331(a), 333(a)(2), and
	)	351(a)(2)(B) Interstate Shipment
Defendant	)	of Adulterated Drugs
	)	

INFORMATION

The United States Attorney charges that:

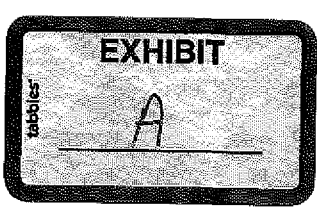
I. GENERAL ALLEGATIONS

At all times material to this Information:

The Defendant

1. **SB PHARMCO PUERTO RICO, INC. ("SB PHARMCO")**, was a corporation organized under the laws of the Commonwealth of Puerto Rico with a principal place of business in Cidra, Puerto Rico. **SB PHARMCO** was an indirect subsidiary of GlaxoSmithKline, plc ("GSK"), a British corporation with a principal place of business in Brentford, Middlesex, England, with publicly traded shares on the London Stock Exchange (ticker symbol: GSK) and the New York Stock Exchange (ticker symbol: GSK).

2. **SB PHARMCO** was engaged in, among other things, the manufacture and interstate distribution of prescription drugs intended for human use throughout the United States, including the District of Massachusetts. **SB PHARMCO** owned and operated manufacturing and packaging facilities in Cidra, Puerto Rico.



3. **SB PHARMCO** was dissolved effective July 3, 2008, but continues to exist under operation of law for three years for purposes of litigation, prosecution, and settlement of its affairs.

The FDA and the FDCA

4. The United States Food and Drug Administration ("FDA") was the federal agency responsible for protecting the health and safety of the public by enforcing the Federal Food, Drug, and Cosmetic Act ("FDCA") and ensuring, among other things, that drugs intended for use in humans were safe and effective for their intended uses and that the labeling of such drugs bore true and accurate information. Pursuant to such responsibility, FDA published and administered regulations relating to the approval, manufacture, and distribution of drugs.

5. The FDCA defined drugs as, among other things, articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man, and articles (other than food) intended to affect the structure of any function of the body of man. 21 U.S.C. §§ 321(g)(1)(B) and (C).

6. Prescription drugs under the FDCA were drugs intended for use in humans which, because of their toxicity or other potentiality for harmful effect, or the method of their use, or the collateral measures necessary to their use, were not safe for use except under the supervision of a practitioner licensed by law to administer such drugs, 21 U.S.C. § 353(b)(1)(A), or drugs limited by the terms of FDA approval to use under the professional supervision of a practitioner licensed by law to administer such drugs, 21 U.S.C. § 353(b)(1)(B).

7. The FDCA prohibited causing the introduction or delivery for introduction into interstate commerce of any drug that was adulterated. 21 U.S.C. § 331(a).

8. Under the FDCA, a drug was deemed adulterated if the methods used in, or the facilities or controls used for, its manufacturing, processing, packing or holding did not conform to or were not operated or administered in conformity with current good manufacturing practice ("cGMP") to assure that such drug met the requirements as to safety and had the identity and strength, and met the quality and purity characteristics, which it purported or was represented to possess. 21 U.S.C. § 351(a)(2)(B).

9. Implementing regulations under the FDCA further defined cGMP required for finished pharmaceuticals, and included, among other specific requirements, the following:

a. *Quality Control Unit.* Drug manufacturers were required to maintain a quality control unit with the responsibility and authority to approve or reject all components, drugs product containers, closures, in-process materials, packaging, material, labeling and drug products and the authority to review production records to assure that no errors had occurred or, if errors had occurred, that they were fully investigated. 21 C.F.R. § 211.22(a) (2003). The quality control unit was to have the responsibility for approving or rejecting all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product. 21 C.F.R. § 211.22(c) (2003).

b. *Contamination and Product Mix-ups.* Separate or defined areas or such other control systems were required for the firm's operations as necessary to prevent contamination or mixups during the course of packaging and aseptic processing. 21 C.F.R. §§ 211.42(c)(6) and (10) (2003). Packaging and labeling facilities were required to be inspected immediately before use to assure that all drug products were removed from previous operations,

and results of such inspections were required to be documented in the batch records. 21 C.F.R. § 211.130(e) (2003).

c. *Equipment.* Automatic, mechanical or electronic equipment or other types of equipment used in the manufacture, processing, packing or holding of a drug product was required to be of appropriate design to facilitate operations for its intended use. 21 C.F.R. § 211.63 (2003). Equipment was required to be routinely calibrated, inspected, or checked according to a written program designed to assure proper performance. 21 C.F.R. § 211.68(a) (2003).

d. *In-Process Testing.* In-process materials were required to be tested for identity, strength, quality and purity as appropriate, and approved or rejected by the quality control unit during the production process, e.g. at commencement or completion of significant phases or after storage for long periods. 21 C.F.R. § 211.110(c) (2003).

e. *Drug Product Testing.* Drug products failing to meet established standards or specifications and any other relevant quality control criteria were required to be rejected, unless satisfactorily reprocessed. 21 C.F.R. § 211.165(f) (2003).

f. *Production and control records.* Drug manufacturers were required to prepare drug product production and control records, and to have those records reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures, before a batch was released or distributed. 21 C.F.R. §§ 211.188 and 192 (2003). Any unexplained discrepancy or the failure of a batch or any of its components to meet any of its specifications were required to be thoroughly investigated whether or not the batch was already distributed, and the investigation was required to extend to other batches of the same

drug product and other drug products that may have been associated with the specific failure or discrepancy. 21 C.F.R. § 211.192 (2003).

10. As part of its mission to enforce the FDCA and protect the public health, the FDA had the authority to enter and inspect, at reasonable times and within reasonable limits and in a reasonable manner, all establishments where drugs were manufactured, processed, packed or held for introduction into interstate commerce or after shipment in interstate commerce. 21 U.S.C. § 374(a)(1). Upon conclusion of the inspection, the FDA had various options, including among others:

a. *Form 483.* A "Form 483," otherwise known as a "Notice of Inspectional Observations," was issued by the FDA to summarize the cGMP deficiencies observed by the FDA inspectors during a particular inspection.

b. *Warning Letter.* A "Warning Letter" was issued by the FDA to document the agency's conclusion that certain manufactured products were adulterated, and to provide notice that unless sufficient corrective actions were implemented, further regulatory action would be taken without notice.

11. Drug manufacturers had certain duties and responsibilities to notify the FDA of information that might impact on the safety or efficacy of the drugs it manufactured, including among others, the following:

a. *Field Alert Reports.* The manufacturer of a drug subject to an approved new drug application was required to notify FDA in a "Field Alert Report" within three working days of receiving information if the information concerned any bacteriological contamination, or any significant chemical, physical or other change or deterioration in the distributed drug

product, or any failure of one or more distributed batches of the drug product to meet the specification established for it under the drug's approved new drug application. 21 C.F.R. § 314.81(b)(1)(ii).

b. *Annual Reports*. The manufacturer of a drug subject to an approved new drug application was required to submit to FDA an annual report with the following information, among other information: (1) a brief summary of significant new information from the previous year that might effect safety, effectiveness or labeling of the drug product, 21 C.F.R. § 314.81(b)(2)(i) (2003); (2) reports of experiences, investigations, studies or tests involving chemical or physical properties, or any other properties of the drug that might affect the FDA's previous conclusions about the safety or effectiveness of the drug product, 21 C.F.R. § 314.81(b)(2)(iv)(a) (2003); and a full description of the manufacturing and controls changes not requiring a supplemental application, listed by date in the order in which they were implemented, 21 C.F.R. § 314.81(b)(2)(iv)(b) (2003).

The Cidra Manufacturing Facility

12. In or about January 2001, following the merger between Glaxo Wellcome and SmithKline Beecham pharmaceutical companies, the **SB PHARMCO** Cidra manufacturing site ("Cidra") became one of GSK's largest manufacturing facilities worldwide and a major supplier of prescription drugs to the United States market. Cidra was a SmithKline Beecham site prior to the merger. Cidra was responsible for making a complex portfolio of drugs, including pills, creams, ointments, and injectables. In addition, GSK designated Cidra to be a new product introduction site for solid dose form products, responsible for moving new compounds from development to commercial production, a technically challenging process.

13. Among other drugs manufactured at Cidra, **SB PHARMCO** made the following drugs for distribution to the United States, including in the District of Massachusetts: Kytril (a sterile injectable anti-nausea medication), Bactroban (a topical anti-infection ointment commonly used to treat skin infections in adults and children), Paxil CR (the controlled release formulation of the popular antidepressant drug, Paxil), and Avandamet (a combination Type II diabetes drug).

14. On or about April 1, 2003, GSK retained a new Site Director for Cidra. In or about July 2003, certain key managers at Cidra resigned as a result of the new Site Director's lack of leadership skills and poor management style. Those managers included, among others, a Quality Assurance Director, the Director of Solids Manufacturing and Packaging, a Manufacturing and Packaging Director, and the Human Resources Director.

15. From in or about April 2003 through September 2004, the Cidra Site Director interfered with the functioning of Cidra's Quality Unit by, for example: ordering all investigative results to be recorded in Spanish to make the results more difficult for GSK Corporate Quality Auditors to review, directing that no investigations into possible process deficiencies be opened without her prior approval, challenging the content of investigative reports prepared by the Quality Unit, and otherwise engaging in inappropriate actions to interfere with the Quality Unit at Cidra.

16. From in or about July 2003 through September 2004, additional managers and other employees at Cidra resigned as a result of the Site Director's interference and management style. Those managers and others employees included, among others, the Packaging Engineering Leader, Validation Manager, Laboratory Manager, Equipment Validation Scientists, Facilities

Validation Scientist, and Computer Validation Scientist. During this time frame, various managers and other employees also complained about the Site Director's interference and management style, including the Director of Quality Assurance and Quality Control, the Director of Compliance, a Quality Manager, and the Human Resource Director. In or about October 2004, the Site Director was removed.

Contaminants in Kytril

17. Kytril was a terminally sterilized injectable anti-nausea medication that was primarily used to treat cancer patients receiving chemotherapy or radiation, and post-surgical patients who experienced nausea. Kytril injection was manufactured at Cidra in the sterile suite. Kytril was manufactured in a Single Dose Vial of 1 ml, and a Multi Dose Vial of 4 ml from which four 1 ml doses could be extracted.

18. As part of the merger between SmithKline Beecham and Glaxo Wellcome, Kytril was divested to another pharmaceutical manufacturer. Under the divestiture agreement, **SB PHARMCO** was required to continue to manufacture Kytril at Cidra until an sNDA to transfer the product was approved.

19. **SB PHARMCO** manufactured Kytril until in or about December 2003, when production was transferred to the acquiring entity.

20. In or about January 2001, following the merger, GSK performed a compliance risk assessment of Cidra and found, among other "high priority" findings, that "[a]wareness needs to be heightened for current and future sterile expectations" and that "[a]septic filling areas had no barrier technology to protect components and point of fill" from contamination. One of the conclusions of the report was that "the aseptic filling area has not been updated with barrier

technology nor has the operation progressed technologically beyond its initial, dated design (circa 1980's)."

21. In or about December 2001, a GSK expert reviewed the Cidra sterile suite and informed **SB PHARMCO** and others that "[f]or the introduction of new or transferring sterile products, the current areas are not appropriate. Detailed improvements will be required which would require a capital project." The expert noted that "[p]resent areas and ways of working would not meet major regulators' (e.g. MCA [European regulators]/FDA) current expectations."

22. On or about July 1, 2002, the FDA issued a Warning Letter to **SB PHARMCO** stating that certain other drug products manufactured at Cidra were adulterated because, among other reasons, **SB PHARMCO** failed to "conduct investigations in a timely manner and to take corrective actions to prevent recurrence." FDA cited as examples delayed investigations involving the water sampling and media fill vials.

23. A follow-up FDA inspection was undertaken in the fall of 2002, and on or about October 9, 2002, the FDA issued a Form 483 observation to **SB PHARMCO** that: "[p]rocedures designed to prevent microbiological contamination of drug products purporting to be sterile were not followed. Specifically, the quality control unit did not assure that adequate systems and controls were in place to monitor sterile areas used to manufacture sterile drug products."

24. On or about April 2, 2003, GSK Global Quality Assurance ("GQA") reviewed regulatory risks at Cidra and identified nine areas of risk required to be controlled to avoid future regulatory enforcement activities. One of the identified risk areas was "sterile manufacturing facility activities and documentation including Kytril Injection." Another identified risk area was

"isolation of objectionable organisms in the water system" and "out of specification events for environmental monitoring of clean equipment."

25. On or about June 13, 2003, **SB PHARMCO** concluded a trend investigation regarding microbial growth in bulk solution in 15 of the 19 Kytril lots manufactured in the first campaign of 2003 at Cidra. The cause was determined to be a bottom outlet flange assembly of glass lined holding tanks that was not disassembled and cleaned, causing microbial growth "TNTC" (too numerous to count). The types of microbial growth included *bacillus cereus, staphylococcus sp., burkholderia cepacia, comamonas testosterone, and stenotrophomonas maltophilia.*

26. From on or about June 23, 2003 until on or about June 27, 2003, GSK GQA audited Cidra against its Quality Management System ("QMS") and found a major deficiency in the sterile manufacturing of Kytril injectable, noting that "[o]perations do not comply with current QMS expectations and a recent campaign has resulted in rejected batches due to high bioburden of bulk solution." QMS auditors concluded that "[c]apital expenditure is necessary to improve current conditions or sterile operations should be discontinued with a sense of urgency."

27. Between in or about April 29, 2003 and May 28, 2003, **SB PHARMCO** released to the company that acquired Kytril for distribution in interstate commerce, including in the District of Massachusetts, certain lots of Kytril that were deemed adulterated because the manufacturing processes and laboratory testing were insufficient to assure the Kytril was of the quality and purity that Kytril was represented to possess.

Contaminants in Bactroban

28. Bactroban was a topical antibiotic primarily used to treat skin infections such as impetigo, in adults and children. Bactroban was manufactured at Cidra both as an ointment and a cream.

29. On or about June 1, 2001, **SB PHARMCO** released Bactroban Ointment Lot 50-1B25 for distribution in interstate commerce even though it was contaminated with *"pseudomonas fluorescens."*

30. On or about November 1, 2001, **SB PHARMCO** issued a Field Alert Report to notify the FDA of the release of the contaminated Bactroban Ointment Lot 50-1B25.

31. On or about February 27, 2002, after additional communications with the FDA regarding the possible health risks of the contaminated Bactroban, **SB PHARMCO** conducted a voluntary recall for Lot 50-1B25.

32. From on or about February 7, 2002 through on or about April 10, 2002, the FDA inspected Cidra.

33. On or about April 10, 2002, the FDA issued a Form 483 to **SB PHARMCO** that noted, among other deficiencies, the following:

> Your Quality Control Unit (QCU) failed to reject drug products not meeting established specifications and quality control criteria. Specifically, your QCU failed to properly review batch records and laboratory analysis reports for Bactroban Ointment lot 50-1B25. Consequently, this batch that was contaminated with *Pseudomonas fluorescens*, an objectionable organism, was released into the market on June 1, 2001. . . .
>
> This oversight was not noticed until Investigation 01-207 was initiated six months later in November 2001 to investigate continuous problems with microbial contamination in Bactroban lots. . . .

> Your firm failed to recognize and evaluate the possible risk of this contamination in a product used to treat impetigo in small children. Your firm did not recall this lot until this issue was brought up during the inspection and a conference call was held with CDER [Center for Drug Evaluation and Research at the FDA].
>
> Your firm failed to investigate and evaluate the reason for recurrent contamination with the organism CDC Group IV c-2 (*Ralstonia paticula*) in Bactroban Ointment and its impact that it might have on the safety and efficacy of Bactroban Ointment. Lots 2901B25, 62-1B25, 84-1B25, 94-1B25 and 105-1B25 were contaminated with this organism and were released and distributed in the market. . . .
>
> Your procedures and actions designed to prevent objectionable microorganisms in drug products not required to be sterile were not effective. . . .

34. In early April 2002, GSK performed a recall investigation at **SB PHARMCO** to determine the root cause of the improper release of the contaminated Bactroban Lot 50-1B25 to market. The audit found that "the final portion of batches were filled as manufacturing operators opened the tank and hand scraped the tank and hopper walls facilitating the filling of the final portion but potentially introducing objectionable organisms as a result of this human intervention," and that a likely cause of the contamination of the Bactroban was that manufacturing operators "could inadvertently introduce the contaminated water into the end of the batch while performing the tank/hopper scrape down." The audit noted that "the practices of disconnecting the chilled water hose from the tank and scraping the tank have been discontinued."

35. On April 23, 2002, GSK responded to the FDA's Form 483 observations and represented in part that **SB PHARMCO** had discontinued "human intervention with holding tanks during filling; the practice of manually scraping the holding tanks during filling; and the practice of disconnecting the hoses supplying the water to the jacket of the holding tanks."

36. In May 2002, as a result of further communications with the FDA, **SB PHARMCO** extended the voluntary recall to five additional lots of Bactroban Ointment that were contaminated with gram-positive organisms that were potentially objectionable.

37. On or about July 1, 2002, the FDA issued a Warning Letter to **SB PHARMCO** stating that certain drug products, including Bactroban Ointment, were adulterated because of the following cGMP violations, among others: (a) failure of the quality control unit to exert its responsibility and authority as required by 21 C.F.R. § 211.22 to reject all drug product that failed to meet the established specifications; and (b) failure to have in place procedures to prevent microbial contamination of products as required by 21 C.F.R. § 211.113, that resulted in release of certain lots of Bactroban to market contaminated with *Pseudomonas fluorescens* and questionable gram-positive organisms.

38. After a new Cidra Site Director was appointed in April 2003, the practice of manually scraping the Bactroban tanks was re-instituted to increase yield of Bactroban ointment, with projected 2003 cost savings of $128,074.

39. In June 2003, the Cidra Site Director's new Director of Manufacturing congratulated the "Semisolids Unit" for salvaging Bactroban that was "being wasted" by the failure to scrape the tanks and hopper, resulting in a reduction of waste from 84 kg to 1.25 kg per lot, an increase in production of 3,343 units, and an increase in output from 88% to 97.7%.

40. On or about October 24, 2003, **SB PHARMCO** released Lot 71-3B25 of Bactroban Ointment for distribution in interstate commerce, including in the District of Massachusetts, despite the fact that the potentially objectionable gram positive organism "*staph spp. not aureus or intermedius*" was identified on equipment used to manufacture the lot.

41. Lot 71-3B25 of Bactroban Ointment was deemed adulterated because the manufacturing processes and laboratory testing procedures were insufficient to assure that the Bactroban was of the strength, identity, quality, and purity that was represented to possess.

Split Tablets in Paxil CR

42. Paxil was a drug used to treat depression, anxiety, and pre-menstrual dysphoric disorder. The controlled release formulation of the drug, Paxil CR, controlled the rate of dissolution and absorption of the active ingredient, Paroxetine, in the body. **SB PHARMCO** manufactured Paxil CR in varying strengths including 12.5 mg, 25 mg, and 37.5 mg strengths.

43. Paxil CR had two layers, one containing the active ingredient ("active layer"), and one containing no active ingredient ("barrier layer").

44. During the manufacturing process, first the active layer was compressed and then the barrier layer was added to the active layer for compression into the final bi-layer tablet. In development at GSK's Crawley plant in the United Kingdom, GSK used a triple-layer press machine to perform these functions.

45. In or about February 2002, **SB PHARMCO** began commercial manufacture of the Paxil CR tablet, the first and only bi-layer tablet manufactured at Cidra. Cidra used three modified single-layer Hata press machines to perform the compression function. The three Hata compression machines used by Cidra were less sensitive in their ability to measure the compression force than the triple-layer press machine GSK used in development.

46. In or about late March and early April 2002, shortly after commercial production began, **SB PHARMCO** observed during packaging that some of the Paxil CR tablets separated between the active layer and the barrier layer. Split tablets contained either only the active layer,

which was absorbed in the body more quickly because of the absence of the controlled release function provided by the barrier layer, or only the barrier layer, which had no active ingredient and no therapeutic benefit for the patient.

47. **SB PHARMCO** classified the split tablet as a "critical defect" which was defined by **SB PHARMCO** as a defect with "a high probability of causing adverse consequences to the patient or consumer, [or] may result in significant deviations in the safety, identity, strength or purity of the product. . . ."

48. On or about April 5, 2002, **SB PHARMCO** completed an investigation of split tablets observed in five different lots of Paxil CR 25 mg and concluded that the most probable cause of the splits was that the compression forces on the active layer in commercial production were slightly higher than the compression forces applied during validation, which could result in the barrier layer not adhering to the active layer. After concluding the investigation, **SB PHARMCO** performed 100 percent visual inspection in an attempt to remove the split tablets, and distributed the five lots.

49. In or about April 2002, **SB PHARMCO** implemented 100 percent visual inspection of all Paxil CR tablets in an attempt to remove split tablets prior to packaging and release of the product to market. As **SB PHARMCO** knew, visual inspection of millions of tablets by human operators was subject to error as a result of the quality of the operator's depth perception, speed of the conveyor belt, and other environmental and human conditions.

50. From in or about December 2002 to February 2003, **SB PHARMCO** conducted a Design of Experiment ("DOE") to determine the cause of the split tablets. The DOE report concluded that "the splitting of CR tablets occurred because the active layer in side A was

compressed using a high pressure, which did not allow a good adhesion of the active layer to the barrier layer." The DOE report recommended, among other things, that **SB PHARMCO** "use lower pressures in the active layer compression process, combined with a load cell that could read those pressures." A load cell was a pressure sensor that detected variations in compression force, and the DOE report concluded that a "load cell of 50 KGF is required to allow the Hata [to] read the low pressures required to control the split situation."

51. Despite its own classification of the split tablet defect as a critical defect, **SB PHARMCO** failed to report the defect or findings of the DOE to the FDA in its 2003 Annual Report, instead informing the FDA that "[n]o significant new information was obtained during this reporting period that might affect the safety, effectiveness, or labeling of Paxil (paroxetine hydrochloride) CR."

52. In or about February 2004, following a series of studies, **SB PHARMCO** instituted manufacturing changes to lower the compression force and to monitor tablet weight, thickness, and hardness during production of the active layer of the 12.5 mg and 25 mg Paxil CR. **SB PHARMCO** did not install the more sensitive load cells on the Hata tablet presses that were necessary to allow the Hata presses to read the lower pressures.

53. After instituting the manufacturing changes, **SB PHARMCO** eliminated visual inspection of the coated 12.5 mg and 25 mg Paxil CR tablets for splits, and substituted statistical inspection. The 37.5 mg tablets continued to undergo 100 percent visual inspection. Statistical inspection involved examination of a sample of 1000 tablets in a batch of approximately 1.5 to 2 million tablets. If no split tablets were found in the sample, the lot was released for packaging and distribution; if splits were found, the lot was 100 percent visually inspected.

54. The change from 100 percent visual to statistical inspection of Paxil CR was a significant change in the manufacturing process, requiring progression and documentation through **SB PHARMCO's** change control process, which included approval by Cidra's Quality Unit. **SB PHARMCO** did not follow the change control process for the implementation of the statistical inspection protocol.

55. Following the change from visual to statistical inspection, **SB PHARMCO** continued to find split tablets of Paxil CR 12.5 mg and 25 mg during packaging, both at Cidra and at GSK's packaging facility in Zebulon, North Carolina, which also packaged Paxil CR for Cidra. Five separate investigations of eight different lots were initiated between April and August 2004 relating to the occurrence of splits in 12.5 and 25 mg tablets after compression. **SB PHARMCO** performed 100 percent visual inspection in an attempt to remove the split tablets and distributed these lots

56. From on or about September 7, 2004 through on or about November 5, 2004, the FDA conducted another inspection of Cidra. The FDA issued a Form 483 to **SB PHARMCO** with the following observation:

> Your firm failed to take adequate corrective and preventive actions to prevent the split tablet defect, classified by your firm as critical defect, in distributed Paxil CR product. Although your process controls include an inspection after the coating process to detect the defect, the defect has been found during the packaging operation of Paxil CR 12.5 tablets and Paxil CR 25 tablets, in approximately 12% and 25% of the batches manufactured/packaged during 2004.
>
> Furthermore, this defect has been found in distributed products and non-distributed products outside GSK-Cidra premises . . . . [providing five examples].

57. During the FDA inspection, on or about September 15, 2004, **SB PHARMCO** re-instituted 100 percent visual inspection of 12.5 and 25 mg Paxil CR tablets.

58. In or about November 2004, **SB PHARMCO** purchased sorting machines to conduct 100 percent automated inspection of the thickness of Paxil CR tablets.

59. Between on or about February 20, 2004 and September 15, 2004, **SB PHARMCO** released certain lots of Paxil CR 12.5 mg and 25 mg tablets for distribution in interstate commerce, including in the District of Massachusetts, that were deemed adulterated because the equipment on which Paxil CR was manufactured was insufficient to ensure that the proper compression force was used on the active layer, and the process controls could not assure that Paxil CR released to market was of the strength, identity, quality and purity that the drug was represented to possess.

Content Uniformity Failures in Avandamet

60. Avandamet was a drug used to treat diabetes. Avandamet was a tablet comprised of two substances blended together in specific amounts. Those substances were rosiglitazone and metformin. Avandamet was made of a small amount of rosiglitazone and a large amount of metformin (e.g. one strength of Avandamet was 1 mg of rosiglitazone and 500 mg of metformin, known as the "1/500 mg" strength).

61. To properly manufacture Avandamet, a homogenous blend of rosiglitazone and metformin was required to ensure all tablets were comprised of the proper blend of the two substances, referred to as "content uniformity." To achieve content uniformity, the rosiglitazone and the metformin were subjected to a granulation process (much like sifting flour to make a cake). Cidra used a wet granulation process that involved adding liquid solution to the powders to achieve the correct density so that a homogenous blend of the two drug substances could be obtained.

62. Commercial production of the 1/500 mg, 2/500 mg and 4/500 mg strengths of Avandamet commenced at Cidra in October 2002. Avandamet was manufactured, in part, in granulation areas known as the Niro 200 suite and the Niro 300 suite at Cidra.

63. In the first few months of production, certain batches of Avandamet failed content uniformity tests. A failed content uniformity test related to rosiglitazone meant that the batch was out-of-specification ("OOS") and contained sub-potent or super-potent tablets.

64. In or about February 2003, one of the GSK GQA auditors commented in connection with a proposed internal mock pre-approval inspection for production of the 2/1000 and 4/1000 mg strengths of Avandamet that "there are many investigations now for content of the 1/500 mg tablet."

65. In or about April 2003, GSK GQA performed the mock pre-approval inspection for the 2/1000 and 4/1000 mg tablets and observed one "Priority 1" finding, which was a finding that "may result in the regulatory agency not having sufficient confidence in process/facility/quality systems/people to allow them to approve the facility as a manufacturer." The Priority 1 finding was "[t]he Niro Fluid Bed Dryer malfunctioned allowing inconsistent drying of the granulation used in Avandamet 1-gram qualification batch, commercial Avandamet 500 mg tablets and commercial Avandia tablets."

66. In or about November 2003, **SB PHARMCO's** sister site in Aranda, Spain complained of defects in tablets received from Cidra, including out-of-specification [i.e. content uniformity failures] tablets.

67. From in or about October 2003 to December 2003, the FDA conducted an inspection of Cidra, and issued Form 483 findings to **SB PHARMCO** that observed the following deficiencies, among others:

a. *Failure to question process.* "The following investigations related to OOS (assay/content uniformity and/or dissolution) obtained for Avandamet have not been questioned in terms of the adequacy of the process for Avandamet tablets . . ."

b. *Failure to take corrective action:* "Failure to take appropriate action against all lots that may be affected by a conclusion included as the assignable cause of a failing result . . . . Although your conclusion assigns as the most probable cause the use of common Rosiglitazone concentrate . . . not all lots using this same granulation concentration were rejected . . . . Furthermore, no action has been taken against any batch that may have been released to the market for distribution."

c. *Inadequate investigations:* "Your 2003 OOS manufacturing investigations related to assay, content uniformity and/or dissolution OOS, obtained for batches of Avandamet . . . are inadequate in that none of these investigations have questioned the adequacy of the process validation used to determine that your manufacturing process is robust and reproducible. Furthermore, your investigations related to these and other failures are not completed in a timely manner . . . ."

68. The FDA conducted another inspection of Cidra from on or about September 7, 2004 through November 15, 2004, and observed continuing deficiencies regarding the Avandamet manufacturing process:

> Since July 2004, your firm has obtained about nine (9) out-of-specification (OOS) results in the content uniformity test for Avandamet as follows [listing lots]. As of November 5, 2004, your firm had not determined the root cause for the failures; if all the OOS results were related to each other; and how to correct the problem. . . . The impact in other lots that used the same in-process materials and obtained passing finished testing results has not been determined. . . .
>
> Investigations of an unexplained discrepancy and a failure of a batch or any of its components to meet any of its specifications did not extend to other batches of the same drug product. Specifically, lot #323-4A67 was recommended for rejection on 9/28/04 due to OOS results for content uniformity test for the Rosiglitazone

> active ingredient. At the closing of the investigation, your firm had not determined the assignable cause for the failure. Twenty seven (27) other lots of Avandamet were manufactured using one or more of this lot's granulations and blends. . . . These lots were not included in the investigation and twenty six (26) of them were released and distributed. There is no assurance that the other lots manufactured under the same manufacturing conditions of the failing lots will have the strength, quality and purity they represent to possess.

69. In early 2005, GSK sent above-site experts to Cidra to determine the root cause of the content uniformity failures regarding Avandamet. Those experts concluded that: (a) a humidity sensor in a Fluid Bed Dryer in the Niro 300 suite had been improperly calibrated for an unknown amount of time, resulting in inappropriate drying times and a shift in granulation moisture content that resulted in poor blending of the metformin; and (b) a spacer or washer had been inserted in the milling machine in the Niro 200 suite that was used to produce rosiglitazone granules, resulting in some over-sized granules of rosiglitazone being used in the final product.

70. Between in or about March 2003 and October 2004, **SB PHARMCO** released certain lots of Avandamet for distribution in interstate commerce, including in the District of Massachusetts, that were deemed adulterated because the manufacturing processes and laboratory testing procedures were insufficient to assure that the Avandamet was of the strength, identity, quality and purity that Avandamet was represented to possess.

Product Mix-Ups

71. During 2002, eight Field Alert Reports were filed with the FDA regarding complaints of product commingling from patients, pharmacies, and hospitals, and nine internal investigations were initiated based on line clearance problems that raised concerns of possible product mix-ups at Cidra.

72. On or about April 2, 2003, a GSK GQA auditor summarized the compliance risks at Cidra against QMS and informed **SB PHARMCO** and others that one of the areas of high risk was product mix-ups and commingling of product.

73. On or about December 2, 2003, the FDA informed **SB PHARMCO** in Form 483 observations:

> Your firm fails to have appropriate procedures and controls in place to prevent mix-ups and/or adverse effects to product from occurring during the manufacturing/packaging process. Furthermore, batches are released by your Quality Unit for distribution although you are aware of findings of mix-ups prior to these batches being released to market.
>
> Product mix-up incidents have been repeatedly occurred [sic] since year 2001 through 2003. Products mentioned in the above examples were approved and released for distribution. Furthermore, complaints related to product mix-ups have been received since year 2001-2003 (period covered during the EI). Nevertheless, you have informed the FDA through FARs [Field Alert Reports] and previous and the current inspection that all incidents are isolated and not related to your manufacturing operation.

74. From in or about at least January 2004 until in or about October 2004, the Cidra Site Director collected rogue tablets from the manufacturing areas and packaging lines, kept them in a gowning hat in her office, and failed to alert site and above-site quality personnel.

75. On or about November 20, 2004, the FDA informed **SB PHARMCO** in Form 483 observations that:

> Procedures for the cleaning and maintenance of equipment are deficient regarding inspection of the equipment for cleanliness immediately before use. Specifically, line clearance's procedures and controls are not appropriate to prevent mix-ups during the manufacturing/packaging processes. The following line clearance's related incidents occurred at the firm during the period of January-August 2004 in products that were released . . . [listing eight separate instances].
>
> About three (3) complaints related to product packaging/mix-ups have been received since 12/2003 that could be related to batches manufactured/packaged within the same period of time and/or the same area of the complaint's lots.

> However, your firm relied on the adequacy of cleaning and line clearance's controls to conclude that it was unlikely that the situation was originated within the packaging area at GSK-Cidra. There is no assurance that adequate controls are in place as to prevent mix-ups during your manufacturing operations . . . .
>
> The responsibilities and procedures applicable to the quality control unit are not fully followed. Specifically, your Quality Unit failed to conduct a thorough investigation of all the events associated with line clearance to prevent mix-ups during the manufacturing/packaging process according to your written procedures. . . . [citing two examples in 10/2004].

76. In or about August 2003, **SB PHARMCO** released Lot 161-3P07 of Paxil CR which contained commingled dosages of Paxil CR for distribution in interstate commerce, including in the District of Massachusetts, which was adulterated because the manufacturing and packing processes were insufficient to assure that the Paxil CR was of the strength, identity, quality and purity that it was represented to possess.

COUNT 1

(21 U.S.C. §§ 331(a), 333(a)(2), 351(a)(2)(B) - Interstate Shipment of Adulterated Drugs)

77. The allegations of paragraphs 1 through 76 are realleged and incorporated herein by reference.

78. Between in or about March 2003 and in or about October 2004, in the District of Massachusetts and elsewhere,

SB PHARMCO PUERTO RICO, INC.

defendant herein, did, with intent to defraud and mislead, cause to be introduced and delivered for introduction into interstate commerce quantities of drugs – to wit Kytril, Bactroban, Paxil CR and Avandamet – that were adulterated in that the methods used in, and the controls used for, drug manufacturing, processing, packing and holding did not conform to and were not operated and administered in conformity with current good manufacturing practices.

All in violation of Title 21, United States Code, Sections 331(a), 333(a)(2) and 351(a)(2)(B).

FORFEITURE ALLEGATIONS

1. Upon conviction of a violation of Title 21, United States Code, Section 331(a),

SB PHARMCO PUERTO RICO, INC.

shall forfeit to the United States pursuant to Title 21, United States Code, Section 334 and Title 28, United States Code, Section 2461(c) any quantities of Paxil CR, Avandamet, Kytril and Bactroban which were introduced into interstate commerce in violation of Title 21, United States Code, Section 331 and/or 351(a)(2)(b);

2. If any of the property subject to forfeiture, as a result of any act or omission of the defendant:

(a) cannot be located upon the exercise of due diligence;

(b) has been transferred or sold to, or deposited with, a third party;

(c) has been placed beyond the jurisdiction of the Court;

(d) has been substantially diminished in value; or

(e) has been commingled with other property which cannot be divided without difficulty;

it is the intent of the United States, pursuant to Title 21, United States Code, Section 853(p), incorporated by reference in Title 28, United States Code, Section 2461(c), to seek forfeiture of any other property of the defendant up to the value of the property subject to forfeiture.

All pursuant to Title 21, United States Code, Sections 334 and 853 and Title 28, United States Code, Section 2461(c), and Rule 32.2 of the Federal Rules of Criminal Procedure.

CARMEN M. ORTIZ
UNITED STATES ATTORNEY

TONY WEST
ASSISTANT ATTORNEY GENERAL
CIVIL DIVISION
U.S. DEPARTMENT OF JUSTICE

By: Susan Winkler
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SUSAN G. WINKLER
SHANNON T. KELLEY
ASSISTANT U.S. ATTORNEYS

MARK L. JOSEPHS
TRIAL ATTORNEY
OFFICE OF CONSUMER LITIGATION

SETTLEMENT AGREEMENT

I. PARTIES

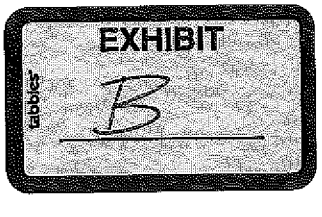
This Settlement Agreement ("Agreement") is entered into among the United States of America, acting through the United States Department of Justice, Civil Division, and the United States Attorney's Office for the District of Massachusetts, and on behalf of, the Office of Inspector General ("OIG-HHS") of the Department of Health and Human Services ("HHS"), TRICARE Management Activity ("TMA"), the Department of Veterans Affairs ("VA"), and the United States Office of Personnel Management ("OPM") (collectively the "United States"); the Relator Cheryl Eckard as identified in Paragraph C of the Preamble to this Agreement ("Relator"); and GlaxoSmithKline LLC, formerly known as SmithKline Beecham Corporation, d/b/a GlaxoSmithKline, and SB Pharmco, Puerto Rico, Inc. (collectively "GSK"). Collectively, all of the above will be referred to as "the Parties."

II. PREAMBLE

As a preamble to this Agreement, the Parties agree to the following:

A. At all relevant times, GlaxoSmithKline LLC, a Delaware Limited Liability Company, had business operations in Philadelphia, Pennsylvania and Research Triangle Park, North Carolina. SB Pharmco Puerto Rico, Inc. ("SB Pharmco") was a corporation organized under the laws of the Commonwealth of Puerto Rico with a principal place of business in Cidra, Puerto Rico. SB Pharmco was an indirect subsidiary of GlaxoSmithKline LLC's UK-based parent corporation, GlaxoSmithKline, plc.

B. At all relevant times, GSK manufactured, distributed, and sold pharmaceutical



products in the United States, including drug products sold under the trade names of Paxil CR, Avandamet, Kytril and Bactroban that were manufactured at SB Pharmco's Cidra, Puerto Rico facility. (the "Covered Drugs")

C. On or about February 25, 2004, Cheryl Eckard ("Eckard") ("Relator") filed a qui tam action in the United States District Court for the District of Massachusetts captioned United States of America ex rel. Cheryl Eckard v. GlaxoSmithKline, et al., Civil Action No. 04-10375 (D. Mass.). On or about October 17, 2008, Eckard filed a Third Amended Complaint in the District of Massachusetts under the same case number and captioned United States of America, et al. ex rel. Cheryl Eckard v. SmithKline Beecham d/b/a GlaxoSmithKline, et al., and this Third Amended Complaint sets forth the current allegations in the qui tam action ("the Civil Action");

D. On such date as may be determined by the Court, SB Pharmco will enter a plea of guilty, pursuant to Fed. R.Crim. P. 11(c)(1)(C) (the "Plea Agreement") to an Information to be filed in United States v. GlaxoSmithKline, Criminal Action No. [to be assigned] (District of Massachusetts) (the "Federal Criminal Action") that will allege a violation of Title 21, United States Code, Sections 331(a), 333(a)(2), and 351(a)(2)(B), namely, the introduction into interstate commerce, of adulterated drugs Avandamet, Paxil CR, Bactroban and Kytril, in violation of the Food, Drug and Cosmetic Act ("FDCA").

E. GSK will be entering into separate settlement agreements, described in Paragraph 1(b) below (hereinafter referred to as the "Medicaid State Settlement Agreements") with certain states and the District of Columbia in settlement of the Covered Conduct. States with which GSK executes a Medicaid State Settlement Agreement in the form to which GSK and the

National Association of Medicaid Fraud Control Units ("NAMFCU") have agreed, or in a form otherwise agreed to by GSK and an individual state, shall be defined as "Medicaid Participating States."

F. The United States alleges that GSK caused to be submitted claims for payment for the Covered Drugs to the Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v ("the Medicaid Program").

G. The United States further alleges that GSK caused claims for payment for the Covered Drugs to be submitted to the TRICARE program (formerly known as the Civilian Health and Medical Program of the Uniformed Services), 10 U.S.C. §§ 1071-1109; the Federal Employees Health Benefits Program ("FEHBP"), 5 U.S.C. §§ 8901-8914; and caused purchases of the Covered Drugs by the Department of Veterans Affairs ("VA") (collectively, the "other Federal health care programs").

H. The United States contends that it and the Medicaid Participating States have certain civil claims against GSK, as specified in Paragraph 2 below, for engaging in the following conduct concerning the manufacture, distribution, and sale of the Covered Drugs that were manufactured at SB Pharmco's Cidra, Puerto Rico facility, at various points during the time period January 1, 2001 through April 1, 2005 (hereinafter referred to as the "Covered Conduct"):

> GSK knowingly manufactured, distributed and sold in interstate commerce certain batches, lots, or portions of lots of the Covered Drugs during the period referenced above, the strength of which differed from, or the purity or quality of which fell below, the strength, purity, or quality specified in the drugs' FDA-approved New Drug Applications ("NDAs") or documents related to the drugs' NDAs, the drugs' labels and/or the standards set forth in the United States Pharmacopeia, in violation of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C.§ 351(b) and (c), which deems such products to be "adulterated," and 21 U.S.C. § 331(a).
>
> More specifically, GSK knowingly manufactured, distributed and sold certain batches,

lots, or portions of lots of: (1) Paxil CR that contained some split tablets causing some consumers to receive either product with no active ingredient and/or product with only the active ingredient layer and no controlled release mechanism; (2) Avandamet that contained some tablets with higher or lower amounts of rosiglitazone than specified; (3) Kytril that was labeled as sterile but was, in some vials, non-sterile; and (4) Bactroban ointments and creams that, in some packages, contained microorganisms.

As a result of the foregoing alleged conduct, the United States contends that GSK sold certain batches, lots, or portions of lots of the Covered Drugs, the strength of which materially differed from, or the purity or quality of which materially fell below, the strength, purity, or quality specified in the drugs' NDAs or related documents as described above, and thereby knowingly caused false and/or fraudulent claims to be submitted to, or caused purchases by, the Medicaid Program and the other Federal health care programs.

I. The United States also contends that it has certain administrative claims against GSK as specified in Paragraphs 3 through 5 below, for engaging in the Covered Conduct;

J. This Settlement Agreement is made in compromise of disputed claims. This Settlement Agreement is neither an admission of facts or liability by GSK, nor a concession by the United States or the Relator that their claims are not well-founded. GSK expressly denies the contentions and allegations of the United States and Relator as set forth herein and in the Civil Action and denies that it engaged in any wrongful conduct, except as to such admissions that SB Pharmco is required to make under the terms of the plea agreement, into which SB Pharmco is entering simultaneously with the execution of this Settlement Agreement. Neither this Settlement Agreement, its execution, nor the performance of any obligation arising under it, including any payment, nor the fact of settlement is intended to be, or shall be understood as, an admission of liability or wrongdoing, or other expression reflecting on the merits of the dispute by GSK.

K. To avoid the delay, expense, inconvenience, and uncertainty of protracted litigation of these claims, the Parties mutually desire to reach a full and final settlement as set

forth below.

III. TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants, and obligations set forth below in this Agreement, and for good and valuable consideration as stated herein, the Parties agree as follows:

1. GSK agrees to pay to the United States and the Medicaid Participating States the sum of Six Hundred Million Dollars ($600,000,000) plus accrued interest in an amount of 3.25% per annum from June 18, 2010 and continuing until and including the day before payment is made under this Agreement (collectively, the "Settlement Amount"). The Settlement Amount shall constitute a debt immediately due and owing to the United States and the Medicaid Participating States on the Effective Date of this Agreement. The debt shall be discharged by payments to the United States and the Medicaid Participating States, under the following terms and conditions:

(a) The Federal Settlement Amount of Four Hundred Thirty Six Million Four Hundred Forty Thousand Dollars ($436,440,000) plus accrued interest in an amount of 3.25% per annum from June 18, 2010, and continuing until and including the day before payment is made under this Agreement, shall be paid by electronic funds transfer pursuant to written instructions to be provided by the United States. GSK shall make this electronic funds transfer no later than seven (7) business days after (i) the Effective Date of this Agreement or (ii) the Court accepts a Fed. R. Crim. P. 11(c)(1)(C) guilty plea in connection with

the Federal Criminal Action and imposes the agreed-upon sentence, whichever occurs later.

(b) GSK shall pay to the Medicaid Participating States the Medicaid State Settlement Amount of One Hundred Sixty-Three Million Five Hundred and Sixty Thousand Dollars ($163,560,000), plus interest accrued on this amount at the rate of 3.25 percent per annum from June 18, 2010, continuing until and including the day before payment is made ("Medicaid State Settlement Amount"). The Medicaid State Settlement Amount shall be paid by electronic funds transfer to an interest bearing account in accordance with the written instructions from the NAMFCU Negotiating Team pursuant to the terms and conditions agreed upon by GSK and the NAMFCU Negotiating Team and as set forth in the Medicaid State Settlement Agreements that GSK will enter into with the Medicaid Participating States.

(c) Contingent upon the United States receiving the Federal Settlement Amount from GSK, the United States agrees to pay, as soon as feasible after receipt, to Relator Eckard a Relator's Share of 22% of the Federal Settlement Amount referred to in subparagraph (a) of this paragraph equal to $96,016,800 plus the pro rata share of the actual accrued interest paid to the United States by GSK on the amount set forth in Paragraph 1 above ("Relator's Share").

2. Subject to the exceptions in Paragraph 6 (concerning excluded claims), below, in consideration of the obligations of GSK set forth in this Agreement, conditioned upon GSK's payment in full of the Settlement Amount, the United States (on behalf of itself, its

officers, agents, agencies, and departments) agrees to release GSK, together with its predecessors, current and former parents, direct and indirect affiliates, divisions, subsidiaries, successors, transferees, heirs, and assigns, and their current and former directors, officers and employees, individually and collectively, from any civil or administrative monetary claim the United States has or may have for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. §§ 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; any statutory provision creating a cause of action for civil damages or civil penalties for which the Civil Division of the Department of Justice has actual and present authority to assert and compromise pursuant to 28 C.F.R., Part 0, Subpart I, 0,45(d); and common law claims of payment by mistake, fraud, disgorgement, unjust enrichment and, if applicable, breach of contract.

3. OIG-HHS expressly reserves all rights to institute, direct, or to maintain any administrative action seeking exclusion against GSK and/or its officers, directors, and employees from Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) under 42 U.S.C. § 1320a-7(a) (mandatory exclusion), or 42 U.S.C. § 1320a-7(b) or 42 U.S.C. § 1320a-7a (permissive exclusion).

4. OPM expressly reserves all rights to institute, direct, or to maintain any administrative action seeking debarment against GSK from the FEHBP under 5 U.S.C. § 8902(b) (mandatory debarment), or (c) and (d) (permissive debarment).

5. TMA expressly reserves all rights to institute, direct, or to maintain any administrative action seeking exclusion against GSK and/or its officers, directors, and employees from the TRICARE Program under 32 C.F.R. §§ 199.9.

6. Notwithstanding any term of this Agreement, specifically removed and excluded from the scope and terms of this Agreement as to any entity or person (including GSK and the Relator) are the following claims of the United States:

(a) Any civil, criminal or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);

(b) Any criminal liability;

(c) Except as explicitly stated in this agreement, any administrative liability including mandatory or permissive exclusion from Federal health care programs and debarment.

(d) Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

(e) Any liability based upon such obligations as are created by this Agreement;

(f) Any liability for express or implied warranty claims or other claims for deficient services;

(g) Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct;

(h) Any liability for failure to deliver services due; and

(i) Any liability of individuals (including current or former directors, officers, employees or agents of GSK) who receive written notification that they are the target of a criminal investigation, are criminally indicted, charged, or convicted, or who enter a criminal plea agreement arising from the Covered Conduct.

7. The Relator, and her respective heirs, successors, attorneys, agents, and assigns, agrees not to object to this Agreement and agrees and confirms that this Agreement is fair, adequate and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B), and expressly waives the opportunity to request a hearing on any objection to this Agreement pursuant to 31 U.S.C. § 3730(c)(2)(B). Conditioned upon payment by the United States of the amounts set forth in Paragraph 1(c) above, the Relator for herself individually, and for her heirs, successors, agents, and assigns, fully and finally releases, waives, and forever discharges the United States, its officers, agents, and employees, from any claims arising from or relating to 31 U.S.C. § 3730; from any claims arising from the Covered Conduct and/or the filing of her Civil Action; and from any other claims for a share of the Federal Settlement Amount; and in full settlement of any claims the Relator may have under this Agreement. This Agreement does not resolve or in any manner affect any claims the United States has or may have against the Relator arising under Title 26, U.S. Code (Internal Revenue Code), or any claims arising under this Agreement. Relator does not release the Medicaid Participating States from any claims that Relator has for a share of any settlement or judgment obtained by the Medicaid Participating States concerning the Covered Conduct.

8. In consideration of the obligations of GSK set forth in this Agreement, and conditioned upon receipt of the payments described in Paragraph 1(c) above, the Relator, for herself, and her heirs, successors, attorneys, agents, assigns, and any other person or entity acting on her behalf or asserting her rights, hereby fully and finally releases, waives and forever discharges GSK, together with its predecessors, current and former parents, direct and indirect affiliates, divisions, subsidiaries, successors, transferees, heirs, and assigns, and their current and

former directors, officers and employees, individually and collectively from any and all liability, claims, allegations, demands, actions or causes of action whatsoever, known or unknown, fixed or contingent, in law or in equity, in contract or tort, under any federal or state statute or regulation, or under common law or that the Relator otherwise would have standing to bring, arising from or relating to the Covered Conduct and that the Relator asserted or could have asserted in, or arising from or relating to, the Civil Action. Provided, however, that the Relator does not release GSK for any claims for attorneys' fees, expenses and costs under 31 U.S.C. § 3730(d).

9. GSK waives and shall not assert any defenses it may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Nothing in this Paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

10. GSK fully and finally releases, waives and discharges the United States, its agencies, employees, servants, and agents from any claims (including attorneys' fees, costs, and expense of every kind and however denominated) which GSK has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to the United States' investigation and prosecution of civil claims arising out of or in connection with the Civil Action.

11. In consideration of the obligations of the Relator set forth in this Agreement, GSK, on behalf of itself, its predecessors, and its current and former divisions, parents, subsidiaries, agents, successors, assigns, and their current and former directors, officers and employees, fully and finally releases, waives, and forever discharges the Relator and her respective heirs, successors, assigns, agents, and attorneys from any claims or allegations GSK has asserted or could have asserted arising from the Covered Conduct or related to the initiation, investigation, and/or prosecution of the Civil Action by Relator and her attorneys. Provided, however, that GSK expressly reserves any defenses or claims with respect to Relator's claim for attorneys' fees, expenses, and costs under 31 U.S.C. § 3730(d), which is reserved pursuant to Paragraph 8 above.

12. Neither the Federal Settlement Amount nor the Medicaid State Settlement Amount shall be decreased as a result of the denial of claims for payment now being withheld from payment by any state or federal payer, related to the Covered Conduct; and GSK agrees not to resubmit to any Medicare carrier or intermediary or any state payer any previously denied claims related to the Covered Conduct, and agrees not to appeal (or cause the appeal of) any such denial of claims.

13. GSK agrees to the following:

(a) Unallowable Costs Defined: that all costs (as defined in the Federal Acquisition Regulations ("FAR") 48 C.F.R. § 31.205-47 and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395ggg and 1396-1396v, and the regulations and official program directives promulgated thereunder) incurred by or on behalf of GSK, its present or former officers, directors, employees,

shareholders, and agents in connection with the following shall be "Unallowable Costs" on government contracts and under the Medicare Program, Medicaid Program, and TRICARE Program:

(1) the matters covered by this Agreement and the related plea agreement;

(2) the United States' audit and civil and criminal investigation of the matters covered by this Agreement;

(3) GSK's investigation, defense, and any corrective actions undertaken in response to the United States' audit and civil and criminal investigation in connection with the matters covered by this Agreement (including attorneys' fees);

(4) the negotiation and performance of this Agreement, the plea agreement, and the Medicaid State Settlement Agreements;

(5) the payments GSK makes to the United States or any State pursuant to this Agreement, the plea agreement, or the Medicaid State Settlement Agreements and any payments that GSK may make to the Relator; and

All costs described or set forth in this Paragraph 13(a) are hereafter "Unallowable Costs."

(b) Future Treatment of Unallowable Costs: These Unallowable Costs shall be separately determined and accounted for by GSK, and GSK shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid Program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by GSK or any of its parents, subsidiaries or affiliates to the Medicare,

Medicaid, or TRICARE Programs.

(c) Treatment of Unallowable Costs Previously Submitted for Payment: GSK further agrees that within 90 days of the Effective Date of this Agreement, it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and VA fiscal agents, any Unallowable costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid Program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by GSK or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. GSK agrees that the United States, at a minimum, shall be entitled to recoup from GSK any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment. Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by GSK or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on GSK or any of its subsidiaries' or affiliates' cost reports, cost statements, or information reports.

(d) Nothing in this Agreement shall constitute a waiver of the rights of the United States to examine or reexamine GSK's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

14. GSK agrees to cooperate fully and truthfully with the United States' investigation relating to the Covered Conduct of individuals and entities not released in this Agreement. Upon reasonable notice, GSK shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. GSK agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by its counsel or agent.

15. This Agreement is intended to be for the benefit of the Parties only. Other than as set forth in this Agreement, the Parties do not release any claims against any other person or entity.

16. GSK agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payers based upon the claims defined in the Covered Conduct.

17. GlaxoSmithKline LLC expressly warrants that is has reviewed its financial situation and that it is currently solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and

548(a)(1)(B)(ii)(I), and will remain solvent following payment of the Settlement Amount. Further, the Parties warrant that, in evaluating whether to execute this Agreement, they (a) have intended that the mutual promises, covenants and obligations set forth herein constitute a contemporaneous exchange for new value given to GlaxoSmithKline LLC, within the meaning of 11 U.S.C. § 547(c)(1); and (b) conclude that these mutual promises, covenants and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties, to the best of their respective knowledge individually, warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which GlaxoSmithKline LLC was or became indebted to on or after the date of this transfer, within the meaning of 11 U.S.C. § 548(a)(1).

18. The United States shall intervene in the Civil Action as to the Covered Conduct and consent to the voluntary dismissal as to GSK and all other defendants and all other allegations set forth in the Civil Action. Within five (5) business days following payment of the Settlement Amount, the United States and Relator shall file a stipulation of dismissal in the Civil Action as follows:

(a) the stipulation of dismissal shall be with prejudice as to the United States' and Relator's claims as to GSK and all other defendants as to the Covered Conduct in the Civil Action pursuant to and consistent with the terms and conditions of this Agreement;

(b) the stipulation of dismissal shall be without prejudice as to the United States and with prejudice as to the Relator as to GSK and all other

defendants and as to all other claims in the Civil Action; and

(c) provided, however, that the following claims shall not be dismissed, unless they are settled, any required United States consent is obtained, and the Court is so informed: (1) Relator's claims for a Relator's Share under the Medicaid State Settlement Agreements; and (2) Relator's claims for reasonable attorneys' fees, expenses and costs pursuant to 31 U.S.C. § 3730(d).

19. Except as expressly provided to the contrary in this Agreement, each party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

20. The Parties each represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

21. This Agreement is governed by the laws of the United States. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Agreement, including any dispute regarding Relator's attorneys' fees, expenses and costs shall be the United States District Court for the District of Massachusetts.

22. For purposes of construction, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

23. Except as expressly set forth herein, this Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of all the Parties.

24. The individuals signing this Agreement on behalf of GSK represent and warrant that they are authorized by GSK to execute this Agreement. The individuals signing this Agreement on behalf of the Relator represent and warrant that they are authorized by the Relator to execute this Agreement. The United States' signatories represent that they are signing this Agreement in their official capacities and they are authorized to execute this Agreement.

25. This Agreement may be executed in counterparts, each of which constitutes an original and all of which shall constitute one and the same Agreement.

26. This Agreement is binding on GSK's successors, transferees, heirs, and assigns.

27. This Agreement is binding on the Relator's successors, transferees, heirs, attorneys and assigns.

28. All Parties consent to the disclosure of this Agreement, and information about this Agreement, to the public.

29. This Agreement is effective on the date of signature of the last signatory to the Agreement ("Effective Date of this Agreement"). Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

30. Notwithstanding any provision of this Agreement, if the guilty plea referenced in Paragraph II(D) is not accepted by the Court or the Court does not impose the agreed upon sentence for whatever reason, this Agreement shall be null and void at the option of either the United States or GSK. If either the United States or GSK exercises this option, which option shall be exercised by notifying all Parties, through counsel, in writing within five (5) business days of the Court's decision, the Parties will not object and this Agreement will be rescinded. If the Agreement is rescinded, the calculation of any statute of limitations period for any civil or

administrative claims brought by the United States arising from the Civil Action shall not include the period from the Effective Date through ninety (90) days after the date of the rescission.

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UNITED STATES OF AMERICA

CARMEN M. ORTIZ
U.S. Attorney, District of Massachusetts

By: Susan G. Winkler / Shannon T. Kelley Dated: 10/26/10

SHANNON T. KELLEY
SUSAN G. WINKLER
Assistant U.S. Attorneys
United States Attorney's Office
District of Massachusetts

UNITED STATES OF AMERICA

TONY WEST
Assistant Attorney General

By: _____ Dated: 10/26/10
JOYCE R. BRANDA
JAMIE ANN YAVELBERG
Attorneys
Commercial Litigation Branch, Civil Division
United States Department of Justice

By:  Dated: 10/25/10

GREGORY E. DEMSKE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services

By: Robert D. Seaman Dated: October 25, 2010

ROBERT D. SEAMAN
General Counsel
TRICARE Management Activity
United States Department of Defense
On Behalf of the TRICARE Program

By: _____ Dated: 10/21/10

SHIRLEY R. PATTERSON
Acting Deputy Associate Director
Insurance Operations
United States Office of Personnel Management

By: _____ Dated: 10/25/2010

J. DAVID COPE
Assistant Inspector General for Legal Affairs
United States Office of Personnel Management

GLAXOSMITHKLINE LLC

By: _____ Dated: 10/26/10

Elpidio Villarreal
Senior Vice President
Global Litigation
GlaxoSmithKline LLC

By: _____ Dated: 10/26/10

Geoffrey E. Hobart, Esq.
Matthew J. O'Connor, Esq.
Covington & Burling LLP
Counsel for GlaxoSmithKline LLC

THE RELATOR

By: Cheryl Eckard Dated: Oct 26, 2010

Cheryl Eckard
Relator

By: Neil V. Getnick Dated: 10/26/10

Neil V. Getnick
Lesley Ann Skillen
Getnick & Getnick, LLP
Counsel for Relator

U.S. Department of Justice

United States Attorney
District of Massachusetts

Main Reception: (617) 748-3100

United States Courthouse, Suite 9200
1 Courthouse Way
Boston, Massachusetts 02210

May 3, 2010

By e-mail and fax
202-778-5281

Geoffrey Hobart, Esq.
Covington & Burling
1210 Pennsylvania Avenue, NW
Washington, DC 20004-3401

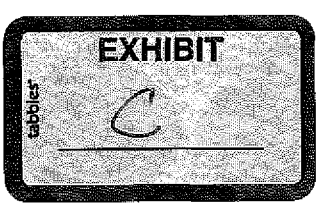
Re: GlaxoSmithKline - Cidra: Tolling Agreement on Statute of Limitations

Dear Mr. Hobart:

This letter confirms and sets forth an agreement between the Office of the United States Attorney for the District of Massachusetts and your client, SmithKlineBeacham Corporation d/b/a GlaxoSmithKline, and all successors and assigns (hereinafter "GSK"). The terms of the agreement are as follows:

1. As you are aware, this Office is presently conducting a joint criminal and civil investigation of your client, GSK, and its officers, employees and agents. That conduct includes, without limitation, allegations that GSK and certain of its officers, employees and agents, may have violated various federal criminal statutes, including but not limited to 18 U.S.C. §371 (conspiracy to defraud the United States), 18 U.S.C. § 1001 (making false or fraudulent statements), 21 U.S.C. § 301, et seq. (Food Drug & Cosmetic Act), health care fraud offenses (e.g. 18 U.S.C. §§ 669, 1347, and 1035), certain civil statutes including but not limited to 31 U.S.C. § 3729 (civil False Claims Act); and certain administrative statutes such as 42 U.S.C. § 1320a-7 (exclusion) and 42 U.S.C. § 1320a-7a (civil monetary penalties) in connection with (a) GSK's production, manufacture, processing, packing, holding, promotion, sale, and distribution in interstate commerce of drugs produced at the facilities in Cidra, Puerto Rico (the "Cidra facilities"), including but not limited to Paxil, Paxil CR, Avandia, and Avandamet (the "Cidra Drugs"), and (b) GSK's communications with the FDA regarding the Cidra facilities and the Cidra drugs (including without limitation regarding inspections, commitments, recalls, seizures, consent decree, and product destruction).

2. In the course of our discussions, this Office has expressed its intention to afford



you and your client the fullest opportunity to provide information to this Office which you deem relevant to matters relating to that investigation. In response, you have advised us that you intend to provide certain information to this Office, and that you wish such information be considered prior to a prosecution decision concerning potential criminal charges resulting from that investigation. You have advised this Office that you and members of your firm will require a further time period to prepare any materials and gather information for presentation to this Office, and to consider and evaluate further information as may be provided by this Office. As a result, this Office and your client have agreed, as more fully set forth below, to toll the applicable statutes of limitations for the offenses described in paragraph one for the time period August 27, 2007 through September 30, 2010 for that conduct described in paragraph one.

3. This Office and your client, GSK, hereby agree that your client will not at any time interpose a statute of limitations defense or any constitutional claim based upon pre-indictment delay to any indictment or count thereof, or to any civil complaint or count thereof, or to any administrative action, which charges or alleges that your client committed any federal offense or violation related to the conduct described in paragraph one, that includes the time period August 27, 2007 to September 30, 2010 in the calculation of the limitations period. Nothing herein shall affect, or be construed as any waiver of, any applicable statute of limitations defenses that GSK may have with respect to the time period prior to and including August 27, 2007, and your client expressly reserves its right to raise any such defense, any provisions of this agreement notwithstanding, except to the extent that your client has waived certain statute of limitation defenses in any waiver agreement(s) with other United States Attorney's Offices or the Department of Justice, which agreement(s) remain in effect.

4. Your client, GSK, enters into this agreement knowingly and voluntarily. GSK acknowledges that the statute of limitations and United States Constitution regarding prejudicial pre-indictment delay confers benefits on it, and it is not required to waive those benefits, and that GSK is doing so after consulting with you because GSK believes it is in its best interest to do so. GSK also acknowledges its understanding that it may be charged with the foregoing criminal offenses and civil and administrative violations and/or any other offenses or violations at any time prior to and including September 30, 2010. GSK further acknowledges its understanding that it may be charged with any offenses or violations not specifically described above, at any time during the relevant statute of limitations period.

5. This agreement relates only to the allegations described in Paragraph one above and any charges or claims based on those allegations. This writing contains the entire agreement between this Office and your client and can be modified or supplemented only by means of a writing signed by this Office and your client.

If your client is willing to enter into this agreement on the terms set forth above, GSK should indicate the same by signing on the spaces provided below and by initialing each page of this agreement. Please return an executed original to the undersigned by May 10, 2010

Very truly yours,

CARMEN M. ORTIZ
United States Attorney

By: /s/ Susan Winkler
Susan G. Winkler
Assistant U.S. Attorney

Dated: 5/10/10
Geoffrey Hobart
Covington & Burling
Attorney for GSK

Dated: 5/12/10
Name: Elpidio Villarreal
Position: SVP - Global Litigation
SmithKlineBeacham Corporation LLC

U.S. Department of Justice

Criminal Division

Office of the Assistant Attorney General *Washington, D.C. 20530*

October 6, 2010

The Honorable Carmen Milagros Ortiz
United States Attorney
District of Massachusetts
1 Courthouse Way
John Joseph Moakley Courthouse
Boston, MA 02210

Attention: Susan Winkler
Assistant United States Attorney

Re: Global Non-Prosecution Agreement for SB Pharmco Puerto Rico, Inc. and GlaxoSmithKline LLC

Dear Ms. Ortiz:

This is in response to your request for authorization to enter into a global case disposition agreement with the business entities known as SB Pharmco Puerto Rico, Inc and GlaxoSmithKline LLC.

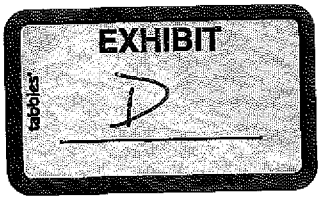
I hereby approve the terms of the plea agreement with SB Pharmco Puerto Rico, Inc., including Paragraphs 5 and 15, and the Side Letter Agreement with GlaxoSmithKline LLC including Paragraphs 1 and 3, in which the United States Attorney's Offices and, with the exception of the Fraud Section, the Criminal Division of the Department of Justice agree not to initiate further criminal prosecutions as set out therein.

You are authorized to make this approval a matter of record in this proceeding.

Sincerely,

Greg D. Andres/MR

Greg D. Andres
Deputy Assistant Attorney General
Criminal Division



ACKNOWLEDGMENT OF AGREEMENT

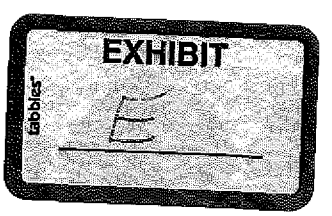
The Trustee of SB Pharmco Puerto Rico, Inc. (the "Trustee") is authorized to execute this Plea Agreement on behalf of SB Pharmco, Puerto Rico, Inc. and to take all such actions as may be necessary to effectuate this Plea Agreement. The Trustee has read this Plea Agreement, the attached criminal Information, and the Civil Settlement Agreement, including all attachments, in their entirety and has discussed them fully in consultation with SB Pharmco's attorney. The Trustee acknowledges that these documents fully set forth SB Pharmco's agreement with the United States. The Trustee further states that no additional promises or representations have been made to SB Pharmco by any officials of the United States in connection with the disposition of this matter, other than those set forth in the Plea Agreement and the attached Civil Settlement Agreement.

Dated: October 26th 2010

Desmond P. Burke
Trustee
SB Pharmco Puerto Rico, Inc.

Dated: 10/26/10

Geoffrey E. Hobart, Esq.
Matthew J. O'Connor, Esq.
Covington & Burling LLP
Counsel for Defendant



NOW THEREFORE, BE IT RESOLVED, that the Company is hereby authorized and directed to enter into the Plea Agreement and Settlement Agreements;

FURTHER RESOLVED, that the Company is authorized and directed to plead guilty to the charges specified in the Information related to the Company;

FURTHER RESOLVED, that pursuant to Section 5.1 of the Plan of Dissolution, the Trustee and/or his duly authorized representatives or attorneys, shall take all actions and deliver any agreements, certificates and documents and instruments with respect to or contemplated by the matters set forth above, including, without limitation, the payment of all amounts, fees, costs and other expenses, necessary or appropriate to effectuate the purpose and intent of the foregoing resolutions and to effectuate and implement the resolutions contemplated hereby;

FURTHER RESOLVED, that any actions taken by Trustee or his duly authorized representatives or attorneys, prior to the adoption of this resolution, that are within the authority conferred hereby, are fully ratified, confirmed and approved as the act and deed of the Company.

IN WITNESS WHEREOF, the undersigned has executed this Consent as of the 26 of October, 2010.

Signed for and on behalf of
SB Pharmco Puerto Rico, Inc.

By: _____
Desmond P. Burke, Trustee